APR 1 3 2001

Wiener lab.
Especialidades para Laboratorios Clínicos
WIENER LABORATORIOS S.A.I.C. - Riobamba 2944 - 2000 Rosario (Sta.Fe) Argentina
Phone (54)41 329191/6 Fax (54)41 325454/325555
Internet: http://www.wiener-lab.com.ar

Section 6 - Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K010421 **"**

Introduction

According to the requirements of 21 CFR 862.1775, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

1) Submitter name, address, contact

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 – Rosario – Argentina
Tel: 54 341 4329191
Fax: 54 341 4851986
Contact person: Viviana Cétola
Date Prepared: October 06, 2000

2) Device name	Proprietary name: Wiener lab. Uricostat enzimático AA Common name: Uric Acid (enzymatic) test system Classification name: Uric Acid, Uricase (Colorimetric) per 21CFR section 862.1775 Device Class I
3) Predicate Device	We claim substantial equivalence to the currently marketed Data Medical Associates, Inc (DMA) URIC ACID test system.
4) Device descriptions	End point method. The WIENER LAB. URICOSTAT ENZIMATICO AA is a method using uricase, peroxidase, dichlorohydroxibencene sulfonic acid (3,5-DHS), 4-amino-phenazone (4-AP) and potassium ferrocyanide. **Principle:** The principle is based on the following reaction system: Uric acid + H_2O + O_2 $\xrightarrow{\text{Uricase}}$ allantoin + H_2O_2 + CO_2 2 H_2O_2 + 4-AP + 3,5-DHS $\xrightarrow{\text{Peroxidase}}$ red quinonimine The amount of uric acid is determined by measuring the absorbance of this pigment.

5) Intended use

Measurement of serum uric acid is largely of use in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failures, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients received cytotoxic drugs. The Wiener lab. Uric Acid Reagent is intended for the quantitative in vitro determination of uric acid in human serum or urine with automated clinical chemistry analyzers.

6) Equivalencies and differences

The Wiener lab. Uric Acid Reagent is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed DMA URIC ACID test system.

The following table illustrates the similarities and differences between the Wiener lab. Uric Acid reagent system and the currently market DMA URIC ACID test system.

	DMA Test System	**WIENER LAB. Test System**
Intended use	Enzymatic method for measurement of uric acid levels in serum and urine.	
Test principle	The principle is based on the following reaction system: Uric acid + H_2O + O_2 $\xrightarrow{UOD}$ allantoin + H_2O_2 + CO_2 2 H_2O_2 + 4-AP + 3,5-DHS $\xrightarrow{POD}$ red quinonimine The amount of uric acid is determined by measuring the absorbance of this pigment.	
Essential Components	UOD – POD – 4-AP – DHS	

Standard	Provided (10 mg/dl)	
Serum and Urine Controls	Available - provided separately	
Instability or deterioration of reagents	Out of specifications values of recently prepared controls. Blank Absorbance higher than 0.500	Values of standard lower than specified Blank Absorbance higher than 0.160
Sample	Serum and urine	
Working Temperature Range	25 – 37°C	
Incubation time	10 minutes at all temperatures	5 minutes at 37° C 20 minutes at 25° C
Stability of final color	20 minutes	30 minutes
Wavelength range of reading.	500 – 530 nm	490 – 530 nm
Calibration	Single point	
Linearity	200 mg/L	
Minimum detection limit	0.3 mg/L	

Expected values	Serum: - Male 36 - 77 mg/L - Female 25 - 68 mg/L Urine: - 205 - 750 mg/24 hs	Serum - Male 25 - 60 mg/L - Female 20 - 50 mg/L Urine: - 205 – 750 mg/24 hs
Intra-assay precision	Normal Control: CV = 2.3% Abnormal Control: CV = 1.0%	Normal Control: CV = 1.75% Abnormal Control: CV = 1.78%
Inter-assay precision	Normal Control: CV = 4.1% Abnormal Control: CV = 2.1%	Normal Control: CV = 2.61% Abnormal Control: CV = 2.39%
Adaptation to automated analyzers	Available	
Sterility conditions	Not required	

7) Conclusion The data above mentioned, shows substantial equivalency to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 3 2001

Dr. Viviana Cetola
Manager, Quality Control and Quality Assurance
Weiner lab.
2944 Riobamba
Rosario, Santa Fe
Argentina

Re: 510(k) NUMBER: K010421
Trade/Device Name: Weiner lab. Uricostat Enzimatico AA
Regulation Number: 862.1775
Regulatory Class: I reserved
Product Code: JHB
Dated: February 8, 2001
Received: February 12, 2001

Dear Dr. Cetola:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 010421

Device Name: Wiener lab.
Uricostat Enzimatico AA

Indications For Use:

The "Wiener lab. Uricostat Enzimatico AA" uric acid test system is an in-vitro diagnostic device intended to measure uric acid in serum and urine.
Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients receiving cytotoxic drugs.

K 010421
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number P. Bernlaur (for J. Cooper)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)